Exhibit B

EXPERT REPORT OF JOYE K. LOWMAN, M.D., MPH

I. BACKGROUND, TRAINING AND EXPERIENCE

I am board-certified in Obstetrics and Gynecology, with a subspecialty board certification in Female Pelvic Medicine and Reconstructive Surgery. I received my medical degree from the University of Pennsylvania and my masters in public health from Columbia University. I completed residency in Obstetrics and Gynecology at Abington Memorial Hospital and a subsequent 3 year accredited fellowship in Female Pelvic Medicine and Reconstructive Surgery at Indiana University, the first accredited program in the country and one of the best surgical training programs in the country. I am a graduate of the CITE (Clinical Investigator Training Enhancement) program at Indiana University, a program sponsored by the National Institute of Health to increase and improve the numbers of clinical investigators in medicine nationwide. I've received extensive training in female pelvic medicine and reconstructive surgery, including vaginal, abdominal, laparoscopic and robotic approaches to pelvic organ prolapse repair and urinary incontinence. This training included advanced surgery using mesh and graft augmentation and surgery for complex female pelvic floor disorders including urinary and bowel fistula, urethral diverticula, recurrent prolapse surgery and surgery for mesh and or prolapse surgery complications. I started the Urogynecology department for the Southeast Permanente Medical Group of Kaiser

Permanente Georgia in 2008, servicing over 250,000 members. I've served as Lead of the department since, where the focus of my practice and our department has been the comprehensive evaluation and management of female pelvic floor dysfunction.

I have considerable experience with prolapse surgery having performed well over 2700 procedures. I have performed native tissue repairs, abdominal sacrocolpopexies (including open abdominal, traditional laparoscopic and robotic sacrocolpopexies), approximately 150 surgeries utilizing the Prolift device, and have used other manufacturers' products for treatment of pelvic organ prolapse. I have substantial experience with the implantation of mid-urethral mesh slings, having performed over 800 mid-urethral slings from various manufacturers, with various approaches. I am very familiar with the Ethicon TVT and TVT-O devices having been fellowship trained in their use and having surgically placed them in approximately 750 procedures. I also have extensive experience in the use of synthetic mesh augmentation to treat pelvic organ prolapse and have used mesh in over 1200 procedures. Additionally, I have managed complications associated with native tissue repairs, sacralcolpopexies, and transvaginal mesh surgeries both that I and other physicians have performed.

I have been trained in the comprehensive evaluation and treatment of female pelvic floor dysfunction using various techniques. My broad exposure during

fellowship training allows me to individualize therapy according to the patient's needs. I am comfortable with the vaginal, laparoscopic, open abdominal and robotic approaches to pelvic organ prolapse repair. I am also comfortable using mesh or graft augmentation and with native tissue repair. I comfortably manage mesh complications, complex female pelvic pain, recurrent prolapse and recurrent or complex urinary incontinence.

I have trained others in performing pelvic floor procedures, including treatment for pelvic organ prolapse. I have conducted studies relating to pelvic reconstructive surgery and treatment as the principal investigator, and have participated in studies conducted with others. Some of the studies have specifically related to use of the Prolift in pelvic floor reconstructive surgery.

Papers detailing the results of these studies have been published in peer-reviewed journals and were recognized as outstanding research at the 28th Annual American Urogynecologic Society national meeting in 2007 and the 34th annual scientific meeting of the Society of Gynecologic Surgeons. A copy of my curriculum vitae, which details my training, education and experience, is attached as **Exhibit "A"** to this report. A list of my publications is also set forth in my CV.

Through my training, clinical and surgical experience and my ongoing review of the literature, I am very comfortable treating pelvic organ prolapse using the Prolift system. I am familiar with the development of Prolift, as well as the

safety, effectiveness, risks and benefits of using the Prolift system to treat prolapse. In preparation for my testimony, I have reviewed some of that literature, as set out in **Exhibit "B."** Materials that support my findings and opinions, including documents that I have reviewed, are identified either in this report or are listed in **Exhibit "B"**. These materials, in addition to my personal experience, knowledge, training, practice and education, have informed the opinions referenced above and which follow as well. I hold all opinions set forth in this report to a reasonable degree of medical and scientific certainty.

For this case, I have reviewed the medical records of Patricia Hammons, as well as available deposition transcripts. I have reviewed the expert reports submitted by the plaintiffs, including specifically the reports of Drs. Elliott, Zipper and Weber.

I have also reviewed the IFUs and Surgical Technique Guide for Ethicon's Prolift device, the Prolift Surgeon's Resource Monograph, Professional Education slides, animations and surgical videos, the Patient Brochures, and other professional education materials.

This report contains my opinions in this case as of the date of this report. My conclusions and opinions are based on the facts presented in the depositions, the physical examinations and complaints of the patient, operative reports and medical records reviewed, as well as the educational materials routinely provided

by Ethicon both for the patient and practitioner, and what is usual and customary in the practice of female pelvic medicine and reconstructive surgery using an evidence based approach. Because I have been trained to perform all of the procedures that can be done to correct pelvic organ prolapse, I understand the pros and cons of each, the particular risks of complication for each, and how to avoid them. I also understand how best to approach resolution of complications when they do occur, because I have done it in my practice for my own patients and for patients who have been referred to me with great success.

II. MY OPINIONS IN THIS CASE

A. Pelvic Organ Prolapse - Background

Pelvic organ prolapse (POP) is the abnormal descent of female pelvic organs such as the bladder, uterus or rectum into the vagina which occurs as a result of damage to and failure of the supporting structures in the pelvis. While aging and vaginal childbirth are major risk factors for the development of pelvic organ prolapse, there are many potential contributing factors, including chronic heavy lifting or straining, smoking, obesity, loss of muscle tone, estrogen loss associated with menopause, family history, pelvic trauma or previous surgery, chronic constipation, chronic cough, and connective tissue disorders.

Pelvic organ prolapse is the most common noncancer indication for hysterectomy in menopausal women in the United States. It affects 50% of parous

women and significantly affects quality of life. Women with prolapse may suffer with discomfort from a vaginal bulge, vaginal ulceration and odorous discharge, voiding difficulties and recurrent urinary tract infections, difficulty with bowel movements and sexual dysfunction. The sexual dysfunction is not only due to pain or discomfort from the prolapse itself, but also to negative body image and embarrassment about the condition. (Barber MD, et al. Continence Program for Women Research Group Sexual function in women with urinary incontinence and pelvic organ prolapse. Obstet Gynecol. 2002;99(2):281-289; Jelovsek JE & Barber MD. Women seeking treatment for advanced pelvic organ prolapse have decreased body image and quality of life. Am J Obstet Gynecol. 2006;194(5):1455-1461;; Handa VL, et al. Female sexual function and pelvic floor disorders. Obstet Gynecol. 2008;111(5):1045-1052.) Other conditions, such as symptoms of overactive bladder when a cystocele is present, may be independent of the prolapse itself (Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013 Apr 30.). A recent population-based analysis found that the lifetime risk of surgery for either SUI or POP was 20.0%. (Wu J et al. Wu et al. Lifetime Risk of Stress Urinary Incontinence or Pelvic Organ Prolapse Surgery. Obstet Gynecol 2014;123:1201-6.) Nearly 30% of all surgery for prolapse and urinary incontinence that was performed in one US study was done for recurrent problems. (Olsen AL, et al.

Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997;89:501-06.). Prevalence of reoperation in a large community-based sample in the Northwest was even higher (43-56%). These numbers are most likely underestimates of recurrence rates as many women who develop recurrent prolapse do not actually seek surgical repair for their recurrence. Younger women (age <60) and women with advanced prolapse (grade 3 or 4) are more likely to experience recurrent prolapse after vaginal repair. (Whiteside JL, et al. Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol. 2004 Nov;191(5):1533-8.) This already overwhelming problem is expected to only increase in significance as the population ages.

B. Pelvic Organ Prolapse — Treatment

Treatment of pelvic prolapse consists of both non-surgical and surgical options. Non-surgical options include physical therapy and behavioral modification and/or use of a pessary. These non-invasive options are often highly successful and are ideal for patients who are poor surgical candidates or who want to avoid invasive intervention. Eighty-five percent of women who attempt pessary use are able to use one successfully. (Lamers BH, et al. Pessary treatment for pelvic organ prolapse and health-related quality of life: a review. Int Urogynecol J. 2011 Jun;22(6):637-44).

Surgical treatment of pelvic organ prolapse is challenging. Vaginal surgery is plagued by recurrence rates of 50% or greater. (Benson JT, et al. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. Am J Obstet Gynecol 1996; 175:1418-22; Lovatsis D, Drutz BP. Vaginal surgical approach to vaginal vault prolapse: considerations of anatomic correction and safety. Curr Opin Obstet Gynecol 2003;15:435-7; Hardiman PJ, Drutz HP. Sacrospinous vault suspension and abdominal colposacropexy: success rates and complications. Am J Obstet Gynecol 1996; 175:612-6; Whiteside 2004; Maher C, et al. Surgical management of pelvic organ prolapse in women. Neurourol Urodynam 2008;37:3-12; Altman D, et al. Nordic Transvaginal Mesh Group (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011 364(19):1826–1836; and many others), and abdominal surgery although more durable, is more invasive, associated with longer operative time and higher cost. The anterior vagina is regarded as the vaginal site that is most prone to recurrent prolapse, possibly due to greater exposure to intra-abdominal strain, greater dependence on intact supportive structures, and potentially greater injury during childbirth. (Whiteside 2004) The Abdominal Sacral Colpopexy (ASC) is the abdominal surgery most often performed to repair pelvic organ prolapse and is considered the "gold standard" for vault repair. This procedure involves the

attachment of a permanent mesh to the vaginal walls that is then attached to the anterior longitudinal ligament of the sacrum. It has been shown to restore normal pelvic anatomy and function better than vaginal repair and its results are longer lasting. (Benson 1996, Maher Cochrane review 2008) It has been theorized that it is the use of mesh, and not the abdominal route, that gives this procedure its durability. General surgeons have used surgical meshes to repair abdominal hernias for decades after learning that using mesh decreased the risk of hernia recurrence by over 50%. (Usher FC, et al. Hernia repair with Marlex mesh. A comparison of techniques. Surgery. 1959 Oct; 46:718-24; Usher FC. Knitted Marlex mesh. An improved Marlex prosthesis for repairing hernias and other tissue defects. Arch Surg. 1961 May; 82:771-3; Luijendijk RW, et al. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med 2000; 343:392-8.) As pelvic organ prolapse is a vaginal hernia of sorts, many pelvic floor reconstructive surgeons began to "augment" their vaginal repairs using mesh or grafts to decrease prolapse recurrence. These mesh or grafts were cut or tailored by the surgeon at the time of surgery, and were difficult or cumbersome to attach to supportive structures like the sacrospinous ligament or to the arcus tendineus fascia safely. The advent of Prolift began in 2000 and was an attempt to make vaginal mesh augmented prolapse surgery easier and more standardized by using an ergonomically designed "kit". (Berrocal J, et al. The TVM Group. Conceptual

advances in the surgical management of genital prolapse. J Gynecol Obstet Biol Reprod 2004; 33:577-587.) This ergonomic design should in theory reduce human error and allow for higher quality, reproducible results and minimize intraoperative risks. The Prolift is a modified sacrospinous ligament fixation, but offers more comprehensive repair due to the "built in" lateral and distal fixation mechanisms. The trocar delivery system allows easier access to the sacrospinous ligament, a structure that lies outside the abdominal cavity, thereby potentially decreasing the risk of vascular and visceral injury. Many randomized controlled trials have compared the Prolift to traditional sacrospinous ligament fixation and have shown the Prolift to be more durable than the sacrospinous ligament fixation with no increase in blood loss or serious bleeding complications. (Halaska M, et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol. 2012 Oct; 207(4):301.e1-7; Svabik K, et al. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol. 2014 Apr; 43(4):365-71; da Silveria DRB, et al. Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. Int Urogynecol J. 2015 Mar; 26(3):335-42.) The use of mesh and the

ability to address all levels of support defects increases the durability of the repair. Thus the system results in a surgery that is less invasive than the ASC, leads to improved success over traditional vaginal prolapse repair, in a shorter period of time, using a standard, and therefore reproducible technique.

This standardized approach has also allowed multi-center comparisons of surgical procedures and their respective outcomes that before were challenging due to wide variations in technique. Before Prolift there were relatively few randomized controlled trials, even for surgeries that had been in existence for many decades. For example, the colporrhaphy had been described in the literature and performed for about 90 years before it was studied in a randomized controlled trial. Similarly, ASC and sacrospinous ligament fixation surgery were performed for many decades before they were studied in a randomized controlled trial. The Prolift has been studied since 2005 and there are over 200 studies on the Prolift to date. These studies were published and presented to pelvic surgeons in the literature and at professional society meetings in 2005 and every year since, and have been sponsored by and independent of Ethicon. These 200+ studies overwhelmingly demonstrate the consistent success of the Prolift at achieving long-lasting anatomic cure.

The use of vaginal mesh augmentation has now been proven in several RCTs and in large meta-analysis to decrease the risk of prolapse recurrence

significantly, particularly in the anterior compartment. (Maher Cochrane Review 2013, Jacquetin B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct; 24(10):1679-86, Table 1 below).

Table 1 Randomised controlled trials comparing polypropylene mesh with traditional native vaginal tissue repairs

Reference	Total number patients	Follow up (months)	Compartment studied	Anatomic cure mesh (%)	Anatomic cure traditional (%)	*p*
Hiltunen et al. [9]	104	12	Anterior	93	62	<0.04
Sivaslioglu et al. [10]	90	12	Anterior	91	72	<0.05
Nieminen et al. [11]	105	24	Anterior	89	59	<0.05
Nguyen and Burchette [12]	75	12	Anterior	87	55	<0.05
Carey et al. [13]	139	12	Anterior Posterior	81	65.6	0.07
Nieminen et al. [14]	202	36	Anterior	87	59	<0.0001
Withagen et al. [15]	194	12	All	90	55	<0.001
Altman et al. [16]	389	12	Anterior	82	48	0.008
Sokol et al. [17]	65	12	All	38	30	0.45

Randomized controlled trials with Prolift and Gynemesh PS, compared to native tissue, have shown better anatomic cure and high levels of patient satisfaction, and significantly improved symptoms and quality of life. (Carey M, et al. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG 2009; 116(10):1380–1386; Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol 2011; 117(2 Pt 1):242–250; Altman D, et al. Nordic Transvaginal Mesh Group (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011 364(19):1826–1836; Sokol AI, et al. One-year objective and functional outcomes of a randomized

clinical trial of vaginal mesh for prolapse. Am J Obstet Gynecol 2012; 206(1):86.e1–86.e9; Halaska 2012; Svabik 2014; da Silveria 2014). Sexual function (PISQ-12) improved as well and there were no statistically significant differences with respect to new-onset dyspareunia for Prolift (9.1%) and the no-mesh group (21.4%) (P=0.60), vaginal diameter, vaginal volume and total vaginal length. And, while there was the reported 15% mesh exposure rate for Prolift, the no-mesh arm had a 15% suture erosion rate. (Sokol 2012)

The use of graft augmented prolapse repair developed as a necessity from the significant failure rates with native tissue repairs. Although mesh augmentation improves durability of prolapse repair, especially in the anterior compartment, it is not without risks. The most common complication with its use (that is unique to using mesh) is mesh exposure, but with correct technique and appropriate patient selection, this risk can be minimized (2%-9%). (2007 Prolift Surgeons Resource Monograph) Other risks associated with mesh augmentation that are less common are mesh extrusion and mesh contraction. These complications may require surgical correction, but are uncommon (0.4%) and can also be minimized with appropriate technique and patient selection. (de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7) Other complications that are not unique

to mesh augmentation include dyspareunia, scarring, granulation tissue formation, de novo urinary incontinence and pelvic pain. Several studies have evaluated these risks and have found them to occur with equivalent frequency in mesh augmented and nonaugmented prolapse surgery.

Cochrane Reviews are systematic reviews of primary research in human healthcare and health policy and are internationally recognized as the highest standard in evidence-based healthcare. The Cochrane Review on the Surgical management of pelvic organ prolapse in women concluded in 2013 that the ASC was associated with a lower recurrence of vaginal vault prolapse and less dyspareunia than the vaginal sacrospinous ligament fixation (SSLF) but was associated with higher cost. They also concluded that standard anterior repair was associated with more recurrent cystoceles than transvaginal mesh augmented repairs. (Maher 2013, et.al)

The American Urogynecologic Society (AUGS), the American Urologic Association (AUA), the International Urogynecologic Association (IUGA) and the American College of Obstetricians and Gynecologists (ACOG) in 2011 acknowledge that there is a role for vaginal mesh augmentation in patients at high risk of recurrence;

"mesh may improve long term anatomic results of surgery as compared to non-mesh repairs for some types of prolapse. Certain patients may benefit from

mesh techniques, and the use of mesh techniques should be a choice that is made after a careful discussion between surgeon and patient" (AUA 2011 position statement on mesh use for prolapse repair),

"grafts are used in repeated surgeries and where significant risk factors for failure exist" (IUGA 2011 inst to patients),

"Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures" "Pelvic pain, groin pain and dyspareunia can occur with pelvic reconstructive surgery regardless of the use or nonuse of mesh… a complication unique to mesh is erosion" (ACOG/AUGS 2011 committee opinion).

Thus, all four major medical societies that govern standards of care in urogynecologic practice acknowledge that there is a role for transvaginal mesh augmentation in high risk patients. These position statements by the largest societies in the world governing practice in urogynecology would not be made in support of a material or device that was "unreasonably dangerous" or "defective" or that caused cancer or degraded in the human body. The societies recognize Prolift's utility which is consistent with my opinion based on the data as set forth in the Prolift studies and my clinical experience. Moreover, additional studies on

Prolift have been published since these statements where Prolift was shown to be safe and effective in primary and recurrent prolapse repair.

No surgical procedure to treat pelvic organ prolapse is without risk. Abdominal surgery, in particular the ASC, increases the risks of ileus and bowel obstruction, abdominal wound infection, abdominal hernia, sacral osteomyelitis, major vessel or visceral injury, DVT and PE and are more morbid due to the invasiveness of entry into the abdominal cavity. Laparoscopic and robotic options also have similar risks as well as risks of insufflation, steep Trendelenburg positioning, and trocar and instrument injury. While mesh exposure occurs with the use of mesh such as that with Prolift, such exposure can occur when mesh is used in sacral colpopexy procedures as well (Nygaard I, et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA. 2013 May 15;309(19):2016-24) and exposure (erosion) of permanent suture material and/or grafts can occur with ASC and in procedures not utilizing mesh. (Abed H, et al.; Systematic Review Group of the Society of Gynecologic Surgeons. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011 Jul; 22(7):789-98; Toglia MR, Fagan MJ. Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture. Am J Obstet Gynecol. 2008 May;198(5):600.e1-4;

Yazdany T, et al. Suture complications in a teaching institution among patients undergoing uterosacral ligament suspension with permanent braided suture. Int Urogynecol J. 2010 Jul;21(7):813-8.)

My personal experience with the Prolift started during my second year of fellowship in 2006. I had just done my first laparoscopic ASC, and it took us 9 hours to complete it. I suffered a nerve injury in that case that I still suffer occasionally from today. I had heard about the Prolift procedure in a lecture when I was a Chief resident. When I performed my first case, as a Fellow, I could not believe how simple it was. It looks very intricate and complex at first, the large mesh with 8 arms laid out on the slides looked ominous, but the procedure is actually simple to perform if you are comfortable with the anatomy and the dissection, and by my second year of fellowship I was very comfortable. The real treat came when I saw my first Prolift patient back in the office for a post-op visit--perfect anatomic support, little to no pain during recovery, and complete patient satisfaction. Her anatomy was just as good as patients whose surgery took me 9 hours to complete laparoscopically. I naively declared then that I would never do another ASC again. I later encountered the mesh erosions, especially since our population had a high tobacco use rate, and early on I dissected superficially for fear of bladder injury. I quickly learned though how to avoid this complication and how to treat it, and decreased my mesh erosion rate to 2%. The Prolift became a

useful tool in my armamentarium. It was my procedure of choice for older patients with large prolapse who declined obliteration, for young patients at high risk for failure with native tissue who were high risk for colpopexy, or for patients with large prolapse of any age who preferred a vaginal route for prolapse repair. The Prolift was a good procedure that benefitted many of my patients. Not having it as an option now is something I lament, as my current procedure of choice, the ASC, is invasive.

The invasiveness of the ASC is mentioned often, but it is difficult to describe how severe and dangerous this procedure can become to those who are not surgeons. Even the many of my colleagues who are surgeons, but who have never encountered the frozen pelvis or abdomen affected by endometriosis or a history of a ruptured appendix, or the dense scar tissue resultant from a history of a gunshot wound to the belly, or the adhesion of the small and large bowel directly to the external iliac artery and vein in a patient with a history of node dissection that all must be taken down to access the sacral promontory in these patients who now have large vaginal prolapse in order to be able to perform an ASC, will not fully appreciate how invasive this procedure can become until they encounter these or similar disease. Even when the anatomy is perfect, serious complications from being in the abdomen can occur. I recently encountered one of my colleagues in the surgeons' locker room in tears. When I asked her what happened, she said that

it was her first day back operating in several weeks since suffering a patient death after an unrecognized bowel injury during an ASC. She had formerly performed many vaginal mesh procedures with great success, but had moved to doing ASC with robotic assistance after the FDA PHN in 2011. She initially was very happy with her surgical results, but now she was devastated. She continued to practice for approximately 3 months, but has since sold her practice and retired from clinical practice.

Most of the time, ASC can be performed safely and effectively without serious injury. It is the reconstructive procedure that I perform most often in my practice. But rest assured, there have been times when I've left the operating room feeling like I just dodged a bullet because of the pulsating common iliac arteries and veins that surrounded my dissection of the sacral promontory, and times that I would have given anything to have had another option that was effective after spending 8 or 9 hours operating because of the abdominal disease I had to treat before I could even attempt the sacral dissection. Often the great risk involved is not related to the procedure itself, but in accessing the anatomy necessary to perform the procedure. As the evidence continues to mount in support of mesh augmentation for correction of cystocele and apical vaginal vault prolapse, more and more surgeons will be performing ASC since transvaginal mesh is under fire. This may lead to many patients suffering morbidity unnecessarily. The vagina is

not an abdominal organ. We should not settle for a procedure that requires abdominal entry, and the dangers therein, to repair it.

Overall, the evidence supports the use of vaginal mesh augmentation to decrease recurrence risk in patients, particularly for those in whom abdominal or lengthy surgery may be unnecessarily risky (obesity, multiple prior abdominal surgeries, medical comorbidities, advanced age, etc.). Most transvaginal mesh complications can be minimized with proper technique and appropriate patient selection. Polypropylene mesh devices, and specifically the Prolift device, while not perfect, are an important surgical option in the treatment armamentarium for pelvic organ prolapse repair.

C. Pelvic Organ Prolapse Repair and Dyspareunia

Dyspareunia is a very common complaint at baseline in women in general and those with prolapse. It is often multifactorial, involving vaginal atrophy, decreased libido, partner issues and other causes. Dietz and Maher noted that up to 64 % of sexually active women attending a urogynecology clinic suffer from female sexual dysfunction (Dietz V, Maher C. Pelvic organ prolapse and sexual function. Int Urogynecol J. 2013 Nov;24(11):1853-7.).

My study found a 16.7% rate of de novo dyspareunia following use of Prolift in 129 patients who had a baseline rate 36.8%. However, dyspareunia is a

risk of all prolapse surgeries and this rate was at the lower end of the rates of de novo dyspareunia seen with other prolapse surgeries:

TABLE 4
De novo dyspareunia after prolapse surgery

Dyspareunia	ASC N = 224 (148)[a] Handa et al[21]	SSLF N = 287 (106)[a] Maher et al[6]	USS N = 110 (34)[a] Silva et al[27]	APR N = 165 (81)[a] Weber et al[18]	Prolift N = 129 (57)[a]
Baseline (preop) dyspareunia (%)	40.5 (60/148)	Unknown	20.6 (7/34)	8.0 (6/81)	36.8 (21/57)
De novo (postop) dyspareunia (%)	14.5 (11/76)	36.1 (22/61)	25.9 (7/27)	19.0 (14/75)	16.7 (6/36)

[a] Number sexually active preop.

Lowman. Does the Prolift system cause dyspareunia? Am J Obstet Gynecol 2008.

Similar to my conclusion that Prolift is not associated with an increased risk of de novo dyspareunia, Dietz and Maher's metanalysis showed that there was no difference in post operative dyspareunia, de novo dyspareunia or PISQ-12 scores.

Although 17% of patients developed de novo dyspareunia, in my study, 85% of patients were satisfied with their results and would have the surgery done again (75% of those with dyspareunia, 83% with de novo dyspareunia). This is consistent with previous reports and highlights the impact of pelvic organ prolapse on quality of life. In addition, patient's willingness to have this surgery again supports the fact that the presence or absence of dyspareunia, although significant, does not determine a woman's overall sexual health.

In the past three years, there have been several randomized controlled trials evaluating Prolift and native tissue repair that show no overall difference in de novo dyspareunia, de novo pelvic pain, sexual functioning by PISQ scores, change in total vaginal length and change in vaginal diameter and volume (Carey 2007;

Withagen 2011; Altman 2011; Sokol 2012; Halaska 2012; Svabik 2014; da Silveria 2014). While there are high levels of preexisting dyspareunia and sexual dysfunction in women suffering from prolapse, Prolift has an overall positive effect on dyspareunia rates and sexual function.

Longer term studies with Prolift and Gynemesh PS have also shown a low rate of reoperation for prolapse, good efficacy and subjective cure/quality of life improvements, and acceptable rates of complications. (Benbouzid S, et al. Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up. Int J Urol. 2012 Nov; 19(11):1010-6; de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan; 206(1):83.e1-7; Miller D, et al. Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results. Female Pelvic Med Reconstr Surg. 2011 May; 17(3):139-43; Jacquetin B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct;24(10):1679-86.).

D. Opinions Regarding Patricia Hammons

1. Use of the Prolift was a safe and effective surgical option for treating Ms. Hammons prolapse and is supported by medical and scientific evidence. Use of the Prolift did not increase her risk of surgical failure, it decreased it, at least in the compartment that it was intended to treat.

The Prolift has been used in thousands of patients and studied in more than 200 scientific trials. It has been studied since 2000 and was brought to market in 2005. It has been proven to achieve excellent success rates (85%) with an acceptable risk profile with data that has amassed over 10 years. In the largest randomized controlled trial to date evaluating vaginal cystocele repair, the Prolift was the trocar-guided procedure of choice, supporting it's widespread acceptance as a safe and effective procedure. (Altman 2011) In this study, 389 women with stage 2 or greater cystocele were randomly assigned to have either an anterior Prolift or anterior colporrhaphy. At one year follow-up, 82.3% of the anterior Prolift group achieved anatomic cure vs. 47.5% of the anterior colporrhaphy group. This is the largest randomized controlled trial to date evaluating cystocele repair. It is considered a landmark study and was published in the New England Journal of Medicine in 2011.

Many other randomized trials have also chosen the Prolift as their method of mesh augmentation. These trials have been published in the New England Journal of Medicine, the International Urogynecology Journal, the American Journal of

Obstetrics and Gynecology and in Obstetrics and Gynecology, the official journal of the American College of Obstetricians and Gynecologists. These journals are the top peer-reviewed journals in our field, and these studies selected the Prolift as their method of mesh augmentation. This supports that the Prolift is not just an acceptable procedure, but it is arguably the procedure of choice (i.e., the industry standard) for trocar-guided mesh-augmented prolapse repair. No other vaginal mesh kits have been studied as often as it has been, especially in randomized controlled trials, and at no time has any study group ever concluded that the Prolift mesh was "defective" or "unreasonably dangerous." (Carey 2007; Withagen 2011; Altman 2011; Sokol 2012; Halaska 2012; Svabik 2014; da Silveria 2014)

The Prolift is less invasive than abdominal sacral colpopexy and offers quicker recovery and return to work which was obviously important to this patient since she returned to work only two weeks after her surgery, and after being cautioned by Dr. Baker that continuing to lift could compromise her repair. I have discussed previously that native tissue repairs are plagued by high failure rates and that the medical community supports the use of mesh augmentation in patients at high risk for prolapse recurrence.

This patient was at high risk for prolapse recurrence for several reasons:

a. Young age

Age <60 at the time of surgery has been shown to be a risk factor for prolapse recurrence. (Whiteside 2004, Weber 2001) Younger women who suffer with prolapse may have inferior tissue quality or may have suffered more neuromuscular injury when compared to their older counterparts. Younger women put greater stress on their surgical repair because of more strenuous activity and have a longer lifetime over which to fail. Ms. Hammons young age at the time of her surgery increased her risk for failure, therefore it was appropriate for the Prolift to be performed to decrease that risk.

b. Tobacco exposure

Tobacco exposure is the leading cause of preventable morbidity and death in the United States, and there are currently >50 million smokers in this country. Smoking impairs epithelial regeneration and collagen synthesis which are integral for an organ to withstand injury or stress. Impaired epithelial regeneration and collagen synthesis leads to weakened tissues. This increases the risk of prolapse and of prolapse recurrence.

c. Obesity

At the time of Ms. Hammons surgery, she was 5'3" tall, and weighed 179 pounds. Obesity is a risk factor not only for the development of pelvic organ prolapse, but for prolapse recurrence.

d. Large prolapse

Women with more advanced prolapse are more likely to experience recurrent prolapse after vaginal prolapse repair. (Whiteside 2004) This may in part be due to poorer tissue quality leading to more advanced disease. (Altman 2011) The staging of pelvic organ prolapse is standardized. The two most often used systems are the Baden-Walker system or the Pelvic Organ Prolapse Quantification (POP-Q) system established by the International Continence Society, AUGS and SGS. (Bump RC, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996 Jul;175(1):10-7.) The staging of prolapse is done to objectively quantify the severity of a patient's condition. This allows not only the ability to be able to evaluate outcomes and perform meaningful comparisons in scientific studies, but it should also be used to determine a patient's treatment strategy and prognosis. For example, uterine cancer is staged, and low stage or grades of uterine cancer often can be treated with hysterectomy and staging alone, whereas more advanced uterine cancers require more aggressive therapy that might include staging and chemotherapy. Ms. Hammons' stage 4 prolapse had a poor prognosis for successful vaginal repair with native tissue. Therefore, mesh augmentation to improve her prognosis and decrease her failure risk was appropriate.

e. Anterior prolapse

Prolapse of the anterior vaginal wall, i.e. a cystocele, is the most difficult prolapse to successfully treat, plagued by a failure rate of 50% or greater. It is also the most common type of prolapse encountered in clinical practice. Out of 300,000 surgeries performed in the US alone for pelvic organ prolapse, anterior colporrhaphy for the correction of cystocele is the single most common operation. (Altman 2011) It is theorized that this part of the vagina is exposed to more abdominal stress or pressure than other vaginal compartments. This may explain why the greatest improvements in success with mesh augmentation have been demonstrated in this compartment. It is this type of prolapse that several randomized controlled trials have shown at least a 50% reduction in failure rate with the use of transvaginal mesh. (Hiltunen R, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007; 110:455–462, Altman 2011) Ms. Hammons' predominant prolapse was a large cystocele. Therefore, it was not only appropriate, but advisable to use mesh augmentation if treatment success was a primary goal.

f. Multiple compartment prolapse

Ms. Hammons had prolapse of the anterior wall (cystocele) and of the apex of the vagina (uterus). Women with more sites affected by prolapse are at higher risk for prolapse recurrence. (Whiteside 2004) Ms. Hammons should have had a

vaginal suspension to decrease her risk of recurrence, and to treat completely the prolapse with which she was already presenting. Despite the fact that she had apical prolapse pre-operatively before all of her surgical repairs, an apical suspension was not performed until her third procedure by Dr. Heit.

g. Chronic lifting/Chronic cough

Chronic increases in abdominal pressure expose the vaginal walls to stress. This increases the risk of the development of pelvic organ prolapse and of prolapse recurrence. Ms. Hammons worked as a stocker in a grocery store. This repetitive exposure to lifting was a major risk factor for failure. She returned to work only 2 weeks after her surgery and presented with prolapse 5 months after her repair. Dr. Baker reports then that "if she keeps lifting" her prolapse may get worse. When she presents to Dr. Lackey with prolapse recurrence he reports, "She continues her job in a grocery store where she does a lot of stocking of shelves and heavy lifting." He concludes that "if she decides on further surgical treatment I may send her to Louisville to see Dr. Heit". Dr. Lackey testifies that the cardiologist's examination of Ms. Hammons for pre-op clearance reported that she admitted to them the symptoms of "shortness of breath with exertion and a dry cough". (57) When she presented to Dr. Heit years later, she was still reporting exposure to lifting and coughing. Dr. Heit notes "aggravating factors: coughing and lifting" when describing her chief complaint and describes her risk factors as "prior

prolapse surgery, prior hysterectomy, chronic smoking, chronic heavy lifting, obesity and vaginal delivery". She smoked 2-3 packs of cigarettes daily for over 30 years as documented on the admission history notes from Good Samaritan Hospital (page 4 of 5, page 35 of 143, MDR00036, MDR00689) and likely had smokers' cough as a result. Part of the anesthesiologist's assessment in this same group of records on page 57 of 143 was that Ms. Hammons had "COPD with 60-90 pack yr h/o tob". On page 43 of 143 they recommended pre-treatment with a nebulizer before her endoscopy procedure, something routinely done for patients with COPD who are at risk for post op bronchospasm which may lead to wheezing and coughing and hypoxia. The most common symptom of COPD is a chronic or daily cough. When Ms. Hammons presented to Dr. Baker her chief complaint was that her prolapse "protrudes when she coughs, lifting and with intercourse", indicating that coughing and lifting are things she did with some frequency. (MDR00023) These two exposures, coughing and lifting, would increase her risk for prolapse recurrence.

In conclusion, the decision to perform a mesh-augmented cystocele repair in this patient with multiple risk factors for recurrence was justified and supported by medical and scientific evidence. The Prolift procedure has demonstrated excellent success and tolerability and therefore was an appropriate choice. In fact, Ms. Hammons' multiple failures in compartments that are traditionally considered less

likely to fail than the anterior compartment are further evidence that she needed mesh augmentation to decrease her failure risk. Furthermore, whereas she developed very large recurrent prolapse in the compartments where mesh was not used, in the compartment where mesh was used, her recurrence was small as evidenced by Dr. Lackey's initial assessment that "the bladder is well supported" and by Dr. Heit's testimony that she did not have a cystocele at the time of his initial consultation. Ms. Hammons presented to Dr. Baker after her initial surgery with large prolapse in the posterior and apical compartments. These were not failures of the anterior Prolift. The anterior Prolift is indicated for the correction of anterior prolapse, or cystocele only. It does not correct apical or posterior wall defects. Ms. Hammons did not fail the anterior Prolift procedure, she simply developed prolapse in the untreated vaginal compartments.

2. Ms. Hammons' dyspareunia is most likely multifactorial and not due to the Prolift procedure. Dyspareunia is a well-known risk with prolapse surgery. The risk of dyspareunia is less with the Prolift than with native tissue repair.

Scarring and dyspareunia can occur with many prolapse surgeries, particularly with native tissue repairs where the nature of the surgery requires suturing fascia in the midline often leading to bunching of tissue in that area, and trimming excess vaginal mucosa, which can lead to scarring, shortened vaginal length, and dyspareunia. (Francis WJ, Jeffcoate TN. Dyspareunia following vaginal operations. J Obstet Gynaecol Br Commonw. 1961 Feb; 68:1-10; Amias

AG. Sexual life after gynaecological operations. Br Med J. 1975 Jun 21; 2(5972):680-1; Kahn MA, Stanton SL. Posterior colporrhaphy: its effects on bowel and sexual function. Br J Obstet Gynaecol. 1997 Jan; 104(1):82-6.) Dr. Lackey testifies in his deposition that this was his approach to posterior repair. (18) The Pelvic Surgeons Network, consisting of over 600 pelvic surgeons including myself, conducted an analysis of available data including efficacy and potential complications with regard to transvaginal mesh placement for prolapse treatment. (Murphy M, et al. Pelvic Surgeons Network. Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse". Int Urogynecol J. 2012 Jan; 23(1):5-9.) There was no difference in dyspareunia rates seen between mesh-augmented surgery and traditional prolapse repair in numerous randomized controlled trials. In the Carey RCT mentioned earlier which included Gynemesh PS, the mesh used in Prolift, the rate of de novo dyspareunia was no different -- 16.7% in the mesh group and 15.2% in the no mesh group at 12 months. Dyspareunia following surgery was considered to be because of vaginal stenosis in three women in the mesh group and five women in the no mesh group. Additionally, two women underwent vaginoplasty for vaginal stenosis and both were from the no mesh group. (Carey 2009). It is almost impossible to identify one procedure that caused dyspareunia in

a patient who has had multiple procedures. As Dr. Heit states in his deposition "anytime you do a surgical incision, whether it be from the hysterectomy itself or from the opening of the anterior vagina to place the anterior vaginal wall mesh, there's always going to be scarring in that area" and therefore difficult to ascertain which procedure caused the scarring and or pain. Dr. Lackey also states, "Anytime you cut on tissue, you can get scar tissue formation, which is not as elastic as the tissue initially. And if it doesn't stretch and give, it can lead to pain. That's true anywhere in the body". (Page 69) He goes on to agree with me when he states, "if there are multiple procedures, you would perhaps not be able to pinpoint the one that is at fault, if any." (Page 75) Thus it is difficult to ascertain which procedure caused the scarring, if any, suffered by Ms. Hammons and whether or not that scarring caused any pain. Ms. Hammons had a hysterectomy, bilateral salpingo-oophorectomy (BSO), and an anterior Prolift performed in May of 2009. It is Dr. Heit's testimony that the BSO likely did not cause her any scarring, and I agree. Heit also testifies that her mesh is causing her painful intercourse, and I disagree. She presented 12 weeks after her surgery with Dr. Baker with the complaint of dyspareunia. He evaluated her and felt her pain was from the posterior vaginal cuff, not from her Prolift mesh. She was subsequently seen by Dr. Lackey several months later and was sexually active. Dr. Lackey's assessment was that her dyspareunia and bulging was "recent and uncomfortable" and his impression was

that her dyspareunia related to her recurrent prolapse. (52) He confirms this in his deposition, and states that he felt her atrophy was also contributing to her dyspareunia. She had vaginal atrophy then and during many of her evaluations which is a known cause of dyspareunia. After Dr. Lackey's surgery, Ms. Hammons was unable to have intercourse at all due to pain. This is not an uncommon occurrence after a posterior repair. She was noted to have vaginal atrophy at his follow-up examination and a recurrent rectocele. Dr. Heit attributed Ms. Hammons' pain to her mesh and tender anterior vaginal wall, but he diagnosed a short vaginal pouch which may have contributed to her dyspareunia, and was unaware that the patient's dyspareunia acutely worsened to the point of apareunia not after Dr. Baker's mesh augmented repair, but after Dr. Lackey's native tissue repair. In Dr. Heit's deposition he confirms that he was unaware of the chronology of Ms. Hammons' prior surgeries as it related to her complaints. This may have changed his clinical opinion that the pain with palpation of the mesh was the cause of her dyspareunia. Dr. Zipper opines that Ms. Hammons is tender to palpation at the vaginal cuff and at the anterior vaginal wall. It is my opinion that Ms. Hammons' dyspareunia was multifactorial and was due to a combination of a shortened vagina, scarring or narrowing from a posterior repair, vaginal atrophy, and rolled or bunched mesh and/or mesh that had been placed on excessive tension. This is evidenced by Dr. Zipper's evaluation which indicates continued

dyspareunia despite the fact that most of the Prolift mesh has been removed. In addition, there is a diagnosis that has not been ruled out, a condition called interstitial cystitis, also known as painful bladder syndrome. This condition is characterized by urinary urgency, frequency, decreased bladder compliance, painful intercourse and pain with palpation of the bladder base or anterior vaginal wall. It is a common problem that is often underdiagnosed. I have not examined Ms. Hammons' at the time of this report, but again, from the information presented, her dyspareunia is likely multifactorial.

Treatment of dyspareunia and pelvic pain should be multimodal. I disagree with Dr. Zipper's assessment that Ms. Hammons' condition has a poor prognosis. I also disagree with Dr. Zipper's assessment that Ms. Hammons' pelvic organ prolapse "would have an excellent chance of responding to native tissue surgery". From my review of this case, Ms. Hammons' should not undergo additional surgery unless she desires relief of her vaginal bulge, and she would certainly not do well with native tissue surgery, especially with a foreshortened vagina. If dyspareunia (unrelated to the prolapse itself) is her major complaint, she should avoid additional surgery and concentrate on therapies to relieve her dyspareunia. I see hundreds of patients with female pelvic pain from various causes and have excellent treatment success. My patients do very well with physical therapy, muscle relaxants when indicated, local hormone therapy, medications or other

treatments for interstitial cystitis, and other therapies. Pelvic pain is treatable, and it is unfortunate that this patient has been counseled otherwise.

3. Ms. Hammons' physical exam findings are not consistent with mesh contraction. Mesh contraction with the Prolift is rare, and there was no evidence of mesh contraction in this case.

Mesh contraction describes a phenomena where tissue that lacks elasticity incorporates into mesh during wound healing and leads to a shrinkage of the mesh. This is usually a global phenomenon, and does not usually affect one aspect or one part of the mesh or vagina. It usually leads to an overall decrease in caliber of the vagina or lack of elasticity to the vagina, and not to an isolated abnormality like rolled or bunched mesh. It is not due to the mesh itself, but to a lack of elasticity of the tissue that incorporates the mesh. It is usually seen in the setting of vaginal atrophy or a short vaginal length at the time of mesh placement. The risk of mesh contraction requiring surgery after a Prolift is uncommon. In a study of 524 Prolift patients with a median follow up of 38 months the rate of surgery for severe symptomatic mesh retraction was 0.4% (2/524). (de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7). To the extent that there is a risk of contraction of tissue following surgery with the Prolift it does not appear to cause any worse overall outcome than the scarring or narrowing that may result with native tissue repair, as

overall there are no statistically significant differences in vaginal diameter, vaginal volume and total vaginal length, nor are the rates of de novo dyspareunia, pelvic pain or change in sexual function significantly different. (Carey 2007; Withagen 2011; Altman 2011; Sokol 2012; Halaska 2012; Svabik 2014; da Silveria 2014) Ms. Hammons had her Prolift performed in May of 2009. In subsequent follow-up visits with Dr. Baker there was no mention of contraction or findings consistent with contraction. When Ms. Hammons was evaluated 12 weeks after surgery, she is reporting painful intercourse. Dr. Baker's assessment is that her pain "is on the back cuff". This area is not in close proximity to the anterior Prolift and would not be a site affected by mesh contraction if it were occurring. Any contraction of the area where the anterior Prolift mesh was implanted would affect the anterior compartment. Dr. Baker advised "to not have as deep of penetration" and reports that "the repair looks great" and that there "is no erosion". She is seen by Dr. Baker 3 months later on 10/26/09 reporting posterior prolapse. She is diagnosed with posterior prolapse, and no problem with the mesh is described. Dr. Baker offers a pessary trial or a posterior Prolift. One month later when she presented to Dr. Lackey, he reports "good anterior wall support" and does not describe any abnormality in this compartment, or pain with palpation of this compartment. It was not until Ms. Hammons presents to Dr. Heit years later, and after her procedure with Dr. Lackey, that an abnormality with the mesh and anterior

tenderness with palpation of the mesh is noted. It is also not until this evaluation with Dr. Heit, after her procedure with Dr. Lackey, that a foreshortened vagina was noted. At no point does Dr. Heit attribute Ms. Hammons questionable mesh exposure or her rolled or bunched mesh or tender mesh to mesh contraction. He testifies to this in his deposition. (208) He attributes the pain from the mesh to it being rolled or bunched and from the anterior vaginal wall being "tense" or "stretched taut" (18). These findings are not consistent with contraction, but might be consistent with excessive tension on the mesh. None of the physicians that actually treated Ms. Hammons in this case documented an impression of mesh contraction, nor do her physical examination findings or findings at the time of her multiple surgeries support this assertion.

4. It was appropriate for Dr. Baker to have received some formal training on the technique of performing the Prolift procedure. Although this is not required of the manufacturer to offer such training, I believe it is an advantage to the surgeons who perform these procedures to be able to participate in such training if they so desire.

There are many devices used in surgery across all subspecialties. Beyond getting FDA clearance for a specific indication for use, providing a description of the device, IFU's, etc., a manufacturer is not required to do much more than make the device available. It is appreciated by surgeons however, when educational opportunities are made available to us, supported by the manufacturer or not, so that we can learn appropriate techniques unique to that particular device and how

to avoid potential complications unique to that particular device. This is not however, our primary source of education when it comes to learning how to perform procedures. Industry sponsored educational opportunities supplement our primary means to surgical education which include residency and fellowship training, proctorships and discourse/videos/procedure labs done with and by colleagues at educational meetings and in other settings. Dr. Baker could have performed the anterior Prolift without any training supported by the manufacturer. It is my opinion that it would be far better, not worse, for him to have been trained. It is the job of medical societies like the American Urogynecologic Society (AUGS), the American College of Obstetricians and Gynecologists (ACOG), and the American Board of Obstetrics and Gynecology (ABOG) to set standards of practice and criteria for those who should or should not be performing certain procedures. ABOG certifies physicians that care for women with obstetric or gynecologic issues. This is what it means to be "board-certified". Dr. Baker was board-certified by ABOG at that time this surgery was performed. He went to professional education about the Prolift, attended live surgeries with expert implanters, read the medical literature, attended CME courses, had the Prolift Technical Guide and IFU, operated on his own patients and assisted his partner on others. By 2009, he had performed many Prolift procedures and knew what his

own outcomes were. He testified that in his opinion the benefits exceeded the risks and he generally obtained good results, better than native tissue repairs.

Dr. Heit testified that he was involved in establishing the guidelines endorsed by AUGS to "help guide credentialing committees at local institutions" so that they are better able to evaluate who should perform the transvaginal placement of surgical mesh for prolapse. (page 87, Heit deposition) He reports that the key points of this document are, "transvaginal placement of surgical mesh for pelvic organ prolapse should only be performed by surgeons who are board-certified or board eligible in obstetrics and gynecology or urology and also have the requisite knowledge, surgical skills and experience in pelvic reconstructive surgery." Dr. Baker obviously had the "requisite knowledge, skills and experience" to perform these procedures as he testifies that many of his patients did very well with the Prolift. Dr. Rohrer thought that Dr. Baker had skills and experience in evaluating and treating patients with these issues because he referred Ms. Hammons to him for evaluation and treatment. At no point in the AUGS society recommendation for credentialing was it stated that physicians performing transvaginal mesh procedures should be required to perform a certain number of procedures annually or be classified as "high volume surgeons" to be able to perform transvaginal mesh procedures for their patients. (American Urogynecologic Society's Guidelines Development Committee. Guidelines for

providing privileges and credentials to physicians for transvaginal placement of surgical mesh for pelvic organ prolapse. Female Pelvic Med Reconstr Surg. 2012 Jul-Aug; 18(4):194-7.) It is unreasonable to expect that patients should be limited to specialty centers or high volume centers to receive care, as there are not enough specialty centers nationwide to meet that need. According to the American Board of Obstetrics and Gynecology, the American Urogynecologic Society, and Daviess Community Hospital, Dr. Baker was qualified to perform transvaginal mesh placement for correction of pelvic organ prolapse. It is not the job of the device manufacturer to make that decision. Furthermore, it is my understanding that device manufacturers do not restrict the use of their devices to certain physicians, rather, hospitals are charged with outlining requirements for credentialing for the surgeons that practice at that particular hospital. Overall, I feel it was appropriate, if not advantageous, for Dr. Baker to receive training about the proper techniques of placing the Prolift, as was recommended in the IFU. Furthermore, restricting or prohibiting him from being trained would not have prevented him from using the Prolift in this case. Rather, it would have decreased his ability to perform the procedure with expertise, and may have increased this patient's risk for complications.

5. There is some discrepancy about whether or not Ms. Hammons suffered a vaginal mesh exposure. If she did, this is a known potential risk with mesh augmentation and Dr. Baker should have counseled her as such. He also should have informed her of the increased risk of this complication in smokers and advised her to quit. Ms. Hammons' did not suffer a mesh extrusion into her bladder as a complication from her Prolift procedure, nor as the result of any alleged defect in the Prolift. She had mesh in the bladder due to poor wound healing after her two cystotomies. Ms. Hammons has unfortunately had several surgeries, all chiefly to repair pelvic organ prolapse. Her multiple surgeries are not the result of her Prolift procedure, but are due to failure of native tissue and graft repair and neglecting to address all prolapsed compartments. This is exactly what the Prolift was developed to prevent.

Ms. Hammons presented to Dr. Baker with uterine (apical) prolapse and a large cystocele (anterior wall prolapse). She had several risk factors for recurrent prolapse after prolapse repair, and fortunately Dr. Baker performed a mesh augmented anterior repair with the anterior Prolift. She never suffered recurrence in this compartment while the Prolift mesh was in place. Unfortunately, Dr. Baker did not perform a vaginal vault suspension at the time of her repair. This left the apical compartment prolapse untreated, as hysterectomy alone does not treat apical compartment prolapse. She presented 5 months post operatively with complaints of prolapse, and she was found to have "a grade 4 rectocele, vaginal cuff prolapse and grade 2 cystocele". This is not anterior Prolift failure. The Prolift cannot, nor can any other procedure performed for anterior compartment prolapse, support the anterior vagina perfectly if the top or apex of the vagina is prolapsing. The

anterior Prolift is in no way an apical suspension procedure and is indicated to treat anterior prolapse only. It is my opinion that the "grade 2 cystocele" reported by Dr. Baker at her follow-up appointment was mild as evidenced by Dr. Lackey's opinion that "the anterior vagina is well supported" when she presented to him for treatment after her Prolift, and by Dr. Heit's testimony that the patient did not have a cystocele when she presented to him for evaluation and treatment after her Prolift. Her small cystocele diagnosed by Dr. Baker was most likely due to her apical prolapse, what we refer to as the "trap door" phenomenon. Her prolapse would likely have been worse if she had not had the Prolift performed.

Ms. Hammons' second surgery was performed by Dr. Lackey for a preop diagnosis of rectocele. She was noted at the time of surgery to also have an enterocele. In the patient's HPI (history of present illness) with Dr. Lackey at her initial consult, he describes her recount of her Prolift surgery and states "Had a hysterectomy and bladder repair in May of this year. Her uterus was coming out and bladder was dropped. She thinks they used mesh and those symptoms are better." He continues, "recently she has noticed something bulging at the vaginal opening and some pain with intercourse." His diagnosis is a grade 2-3 rectocele, thin rectovaginal septum, mild vaginal atrophy, and well-supported bladder. He states "She wants this (her prolapse) surgically repaired as intercourse is painful and she does not want to deal with it." He testifies that it is his impression that Ms.

Hammons' dyspareunia at this time was due to her prolapse. His plan was to perform a posterior repair. An enterocele was encountered at the time of surgery and was also repaired. These procedures were not performed as a result of her Prolift surgery, but to correct prolapse in previously untreated compartments.

Ms. Hammons was seen by Dr. Lackey two years later for follow-up. She complained of inability to have intercourse *since her surgery with him* due to pain. Dr. Lackey reports that after her surgery she did well until one month prior to seeing him, although he also states that she has been unable to resume intercourse since her surgery with him 2 years prior because of vaginal pain. He testifies that it was his impression that Ms. Hammons' dyspareunia at this point was due to his surgery, not her Prolift surgery. His physical exam documents an atrophic vagina and a rectocele that is minimally tender. He reports that he can feel her mesh underneath the bladder but does not report that palpation of the mesh elicits pain. He reports that she is not incontinent. His assessment is "other than this pressure and bulging, she really is not symptomatic" giving the impression that her dyspareunia was not a major complaint. He plans to manage her expectantly unless her condition worsens. She returned for follow up with him 8 months later with a new complaint of urinary incontinence without sensation. Dr. Lackey then refers her to Dr. Heit for further management.

Ms. Hammons' third surgery was performed by Dr. Heit 3 years later. She presented to him with a complaint of recurrent prolapse, dyspareunia and insensible urine loss. Although he documents dyspareunia as a diagnosis, this does not appear to be a major complaint for her at that time since it was not described at all in her HPI. His diagnoses include anterior mesh erosion, UTI (urinary tract infection), stress incontinence, rectocele, enterocele and dyspareunia. He recommends mesh removal, posterior repair and abdominal sacral colpopexy. He testifies that he later changed his mind about mesh removal because it seemed that dyspareunia was not a major complaint for the patient and that her primary complaint was urinary incontinence. (190) There was also some discrepancy about her vaginal mesh erosion/extrusion. It was only after she failed the usual therapies for overactive bladder that he decides to proceed with surgery. He planned to excise the anterior vaginal mesh and perform a sacrospinous ligament fixation and posterior repair using an allograft. During the procedure, he created two inadvertent cystotomies while dissecting out the mesh, well known potential complications with mesh excision in this compartment. He placed a left ureteral stent prior to repairing the cystotomies. He later takes her back to the operating room for operative cystoscopy to excise mesh from her bladder. He discovered the bladder mesh at the time of office cystoscopy to remove the Left ureteral stent. As Ms. Hammons' first surgery with Dr. Heit was performed primarily for

incontinence complaints attributed to her mesh, but likely not caused by her mesh, and a questionable mesh erosion that did not appear to be confirmed at the time of surgery, her history of having a Prolift procedure was not the primary reason for her return to the operating room. Her return to the O.R. with Dr. Heit the second time was to repair a complication caused at the time of his first procedure, not due to having a complication from the initial Prolift surgery. Dr. Heit implies in his medical record that the cystotomies and the mesh in the bladder somehow indicate that her mesh extruded into the bladder after her Prolift or that the mesh was already in the bladder prior to his first procedure. But he also testifies that " I am—I do not believe that mesh migrates" (page 208) which would mean that the mesh would have been put in the bladder at the time of Dr. Baker's Prolift procedure. Dr. Baker performed cystoscopy after his Prolift procedure and there was no bladder injury at that time. Usually if there is a foreign body in the bladder, the patient will complain of irritative voiding symptoms, she will demonstrate blood in her urine (hematuria), foul odor to the urine or recurrent UTIs. Ms. Hammons was seen by several doctors after her Prolift surgery and never demonstrated these findings or had these complaints. Dr. Heit had to evaluate the exact area where mesh was later noted to be eroded to be able to place a left ureteral catheter during his first surgery. Regardless of whether or not he had performed pre-operative cystoscopy prior to his initial procedure, a mesh erosion

into the bladder just lateral to the left ureteral orifice that he had to cannulate would have been hard to miss, especially since he had to repair two cystotomies in that area. It is my opinion that Ms. Hammons did not suffer a mesh extrusion (mesh migration into her bladder after her Prolift procedure), but suffered a complication of poor wound healing after two cystotomy repairs and partial mesh excision. Dr. Zipper reports that he too believes the mesh found in the bladder was a complication of Ms. Hammons' cystotomy repairs. Thus, her fourth and final return to the operating room to remove mesh from her bladder was not a complication of the Prolift surgery, but a complication of impaired healing after her third surgery.

6. Ms. Hammons does not have impaired bladder compliance or overactive bladder because of her Prolift procedure. Her overactive bladder is most likely multifactorial, but her biggest risk factor is her heavy smoking.

Overactive bladder (impaired bladder compliance) is a common condition suffered by many women. There are many risk factors, including a history of pelvic surgery (hysterectomy, myomectomy, childbirth, prolapse repair), exposure to bladder irritants (coffee, tea, tobacco, alcohol, carbonated beverages, citrus juices), aging and menopause, prolonged catheterization, incomplete bladder emptying or voiding dysfunction, presence of a cystocele and vaginal atrophy. Ms. Hammons has several of these risk factors, and all are likely contributing to her overactive bladder. She has had several episodes of prolonged catheterization,

once after her surgery with Dr. Baker and again after her surgery with Dr. Heit. She has had multiple pelvic surgeries and is a heavy smoker. She has a large recurrent cystocele according to Dr. Zipper which is associated with overactive bladder symptoms. She has been diagnosed with vaginal atrophy many times throughout her medical record. Her biggest risk factor for impaired bladder compliance and urinary urgency, frequency and urgency incontinence is her heavy smoking.

Cigarette smoking is a known cause of bladder irritation and increased contractility. Smoking increases the excretion of carcinogenic chemicals in the urine 50% (35-97%) above nonsmoking levels and decreases tryptophan metabolism by 14-40%, thereby increasing tryptophan derivatives. Derivatives of tryptophan are carcinogenic to the bladder. (Kerr WK, et al. The effect of cigarette smoking on bladder carcinogens in man. Can Med Assoc J. 1965 Jul 3;93:1-7.) A study of over 2,000 women showed a "dose-response relationship that explains smoking's effect on bladder control. The more women smoke, the more frequent and strong their need to urinate", Dr. Sharon Knight, MD, a urogynecologist and associate professor of Ob/GYN at the Univ of California San Francisco explains, "Some explanations (for the dose response seen in this study) have been proposed, such as nicotine-induced bladder contractility and some other toxins that can be bladder irritants". (online commentary about the following report published in the

Green Journal) In the study Dr. Knight references, urgency and frequency were found to be 3 times more common among current smokers than never smokers. (Tähtinen RM, et al. Smoking and bladder symptoms in women. Obstet Gynecol. 2011 Sep; 118(3):643-8.). Another study published in the Journal or Urology found that women smokers were twice as likely to develop lower urinary tract symptoms, particularly storage symptoms compared to nonsmokers. (OR=2.15, 95% CI:1.3-3.56, p=0.003). (Maserejian, N., et al. Are physical Activity, smoking and alcoholic drinking associated with development of lower urinary tract symptoms in men or women? Results from a population-based observational study. J Urol. 2012 Aug;188 (2):490-495.) A recent review of treatment strategies to improve bladder control lists smoking cessation as a top strategy to resolve urinary urgency, frequency and urgency incontinence highlighting the fact that smoking leads to abnormal bladder contractions. (Wyman JF, et al. Practical aspects of lifestyle modifications and behavioural interventions in the treatment of overactive bladder and urgency urinary incontinence. Int J Clin Pract. 2009 Aug;63(8):1177-91.)

Many women have overactive bladder or impaired bladder compliance and have no identifiable risks. The Prolift and other prolapse repairs have been associated with postoperative de novo incontinence, but usually this is stress incontinence. In any event, there are several options for therapy for both stress and

overactive bladder incontinence that are very effective and minimally invasive, including medications, behavioral modifications, physical therapy, periurethral collagen injections, mid-urethral slings, anticholinergic therapy, Interstim and botox. (Gormley EA, et al.; American Urological Association; Society of Urodynamics, Female Pelvic Medicine. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015 May;193(5):1572-80.) But in my opinion, Ms. Hammons will not achieve bladder control without smoking cessation.

A diagnosis that has not been ruled out and should be considered in this case is interstitial cystitis. This condition, also known as painful bladder syndrome, is characterized by urinary urgency, frequency, decreased bladder compliance, painful intercourse and pain with palpation of the bladder base (anterior vaginal wall). It is a common problem that is often underdiagnosed. Its cause is unknown, but effective treatments are available.

Ultimately Ms. Hammons has multiple risk factors for poor bladder control, and I do not believe her bladder symptoms are a result of her Prolift procedure.

In summary:

- The design of the Prolift device implanted in Ms. Hammons was at all times appropriate for its intended use and was an important treatment option in the armamentarium of physicians treating pelvic organ

prolapse. The data has consistently shown this product to achieve anatomic cure in 80-90% of cases with an acceptable rate of complications.

- At all times pertinent to Ms. Hammons' claims, Ethicon adequately apprised physicians practicing pelvic reconstructive surgery of the method for implantation and use, as well as the risks associated with the use of Prolift. It is clear that Dr. Baker warned Ms. Hammons of the pertinent risks including dyspareunia and mesh exposure as reflected in his medical records and deposition testimony.
- Use of the Prolift in Ms. Hammons was within the standard of care for treating her large pelvic organ prolapse in the setting of multiple risk factors for recurrence. It was used to treat her cystocele and was the only prolapse procedure that she had that was actually effective at achieving and maintaining anatomic cure.
- Any "bunched" or "rolled" mesh observed in the midline underneath the proximal urethra and distal bladder base after Ms. Hammons' Prolift procedure was not caused by an inherent defect in the Prolift mesh. Prolift mesh "rolled" in any compartment is not described or considered to be a common potential complication with Prolift procedures. This is not a known sequelae of contraction. Any

observed rolling or bunching of mesh after the Prolift in this case was most likely due to improper technique in implantation, lack of supporting the vaginal apex and resultant avulsion of the mesh from its sutured position once the apex prolapsed, or a combination of both. In the over 200 trials where the Prolift has been studied, “rolled mesh” has not been identified as a common complication. Thus, any complaints of dyspareunia and pain in the area of any observed "bunched mesh" would not be due to a defect in the Prolift mesh, but to improper implantation technique or mesh avulsion.

- Dyspareunia is a known risk of any pelvic surgery. Since a hysterectomy was performed at the time of Ms. Hammons’ anterior repair with Prolift and she subsequently required rectocele and enterocele repair, it is impossible to say with any degree of medical certainty that Ms. Hammons current claims of dyspareunia and pelvic pain would not have occurred independent of the Prolift surgery. Put another way, but for Prolift she still had a significant risk of dyspareunia and pelvic pain. In addition, she has other diagnoses (atrophy and foreshortened vagina) and potential diagnoses (interstitial cystitis) not caused by the Prolift that are known to cause pain. In any event, she was counseled that dyspareunia could result

from her surgery as documented in her preoperative consultation note with Dr. Baker and this risk would have persisted had Prolift not been used to correct her prolapse. Pelvic examination of Ms. Hammons by Dr. Heit revealed a mildly shortened vagina of 7 cm. Shortened vaginal length is commonly associated with hysterectomy and enterocele repair and is not common after Prolift. None of the randomized controlled trials with Prolift demonstrate a statistically significant difference in total vaginal length, or worsening or change in vaginal diameter, vaginal volume, de novo dyspareunia, pelvic pain or change in sexual function. (Carey 2007; Withagen 2011; Altman 2011; Sokol 2012; Halaska 2012; Svabik 2014; da Silveria 2014)

- Ms. Hammons' medical records reflect a history of heavy smoking (2-3 packs per day) despite having been advised to quit smoking. It is well-known that smoking increases the risk of pelvic mesh exposure. It is my opinion that her smoking substantially contributed to her mesh exposure, if indeed she had a mesh exposure.
- Incontinence is a risk associated with any pelvic surgery including prolapse surgery not using mesh. Ms. Hammons tobacco exposure, age, pelvic floor disease resulting in multiple prolapses, and obesity are likely contributing to any incontinence Ms. Hammons complains

of. However, based upon Dr. Heit and Zipper's testimony, any prior incontinence experienced by Ms. Hammons subsequent to her Prolift surgery has resolved. Moreover, Ms. Hammons predominant incontinence complaint was urge incontinence or "impaired bladder compliance", and not stress incontinence. Urge incontinence is not typically associated with the Prolift procedure. The causes of urge incontinence are usually multifactorial as it is in this case, and highly associated with tobacco exposure. Therefore, it is my opinion that any current incontinence, urinary urgency or frequency complained of is not related to Ms. Hammons Prolift surgery.

- Ms. Hammons required multiple surgeries for apical and posterior prolapse. Her most recent medical examinations reveal that she has again failed, for the second time, a rectocele and apical prolapse repair despite the use of a surgisis graft as she continues to have a stage 3 pelvic organ prolapse. In my opinion neither the original rectocele nor the subsequent recurrent prolapses derived from Ms. Hammons Prolift surgery. Rather, the anterior repair, until the mesh was removed, was the only effective surgery she had. In my opinion, if mesh had been used to repair her rectocele and apical prolapse as Dr.

Baker suggested with a posterior Prolift initially, she would have achieved cure in all vaginal compartments.

E. Opinions Regarding Adequacy Of IFU And Patient Brochure

At all times pertinent to Ms. Hammons claims, Ethicon adequately apprised physicians practicing pelvic reconstructive surgery of the risks associated with the use of the Prolift. From my perspective as a pelvic floor reconstructive surgeon, associated risks were adequately described in the Prolift IFU and professional education materials. While those materials are important, my colleagues and I do not rely on IFU's or instructions from device manufacturers as our primary means of learning about the products used in surgery, the methods of using or implanting surgical prosthetics, or risks associated with their use. Rather, we learn how to perform any surgery, including the Prolift, as previously stated, in residency, fellowship and by proctorship.

The original Prolift IFU warned of several risks including damage to nerves, vessels, bladder and bowel, inflammation, adhesions, erosion, extrusion and scarring that results in implant contraction. It is understood in the medical and scientific communities that these complications may cause pain and dyspareunia, as well as the need to reoperate.

Additionally in 2008 the FDA published a public health notice which highlighted these risks for pelvic surgeons. The professional education materials

and 2007 Prolift surgeon monograph, which supplement the IFU, warn of complications like contraction, erosion, pain and dyspareunia and the management of these complications. The Prolift Patient Brochures available for dissemination by physicians to use in discussing the Prolift with their patients provided adequate information to lay persons to supplement discussions with their physicians regarding treatment options for prolapse repair. The Prolift Patient Brochure from 2008 identifies several risks such as those Ms. Hammons has complained of:

> "Complications associated with the procedure include injury to blood vessels or nerves of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh. Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition."

However, brochures were never meant to replace the surgeon-to-patient dialogue or the informed consent process, nor do or should physicians utilize brochures as substitutions for consenting their patients prior to any surgical

procedure. It is up to the surgeon, based on his or her education, training, experience and study of the literature, to make informed judgments and counsel patients.

F. Professional Education And Its Adequacy

It is not a device manufacturer's responsibility to train surgeons, but it is a positive thing for them to offer supplemental surgical exposure to "experts" in the fields in which they offer devices, because it allows surgeons, including myself, exposure to continuing medical education from those that have the most experience with their products. Learning and improving is a process for surgeons that is never done. This is why continuing medical education is not just encouraged, but required to maintain board certification and medical licensure. It is from high volume surgeons with great expertise that lower volume or less experienced surgeons become better surgeons. Every patient in the country cannot go to one or two high volume surgeons in specialty centers to have their prolapse fixed or their incontinence treated. Every surgeon should be given the opportunity to improve their surgical skills. The training that Ethicon offers or supports should supplement the surgeon's training from residency, fellowship and proctorships, and should not be the surgeon's primary source of surgical expertise. The professional education offered by Ethicon has been more than adequate, but exceptional in my opinion.

G. Surgeons Resource Monograph And Its Role

The Surgeons Resource Monograph is a supplemental description of the indexed procedure that outlines in detail the parts that are included in the Prolift procedure box, the way that the procedure is performed and other information that might be useful to the operating surgeon, particularly if there are questions or confusion about certain aspects of the procedure or the product itself. The Monograph provided by Ethicon is more than adequate to provide the aforementioned information. This information is not given to "teach" a surgeon how to perform this procedure, but to supplement what the surgeon has learned in his/her surgical training. Learning to perform this procedure should be done through education and training in residency or fellowship or by cadaver lab training and/or proctoring, not by reading the surgeons monograph, or an IFU, or any other educational material provided by the device manufacturer in isolation.

III. FEES FOR CONSULTING IN THIS CASE

I am serving as a paid expert consultant to Troutman and Sanders regarding the matters of this case.

IV. CONCLUSION

The Prolift was an appropriate therapeutic choice in this case. It was consistent with the standard of care, was not defective, and effectively treated Ms. Hammons' cystocele, the purpose for which it was intended. Ms. Hammons unfortunately experienced complications well-known to Dr. Baker, warned of in

Ethicon materials, the literature and the 2008 FDA public health notice, and discussed in the informed consent process per Dr. Baker. These complications and her current condition are not due to her having had the Prolift procedure specifically, but are complications common to prolapse surgery in general, and are a reflection of the persistence and severity of her pelvic floor dysfunction and continued risk factor exposure. It is my opinion that the IFU, Patient Brochures, Professional education materials and other information provided were adequate and sufficient to apprise physicians of the information they needed to properly offer the Prolift to their patients, including risks associated with its use, given their expected base of knowledge of prolapse surgery from their education and training. I hold all the opinions expressed in this report to a reasonable degree of medical certainty.

s/ Joye K. Lowman

Joye K. Lowman, M.D., M.P.H.
August, 2015

Appendix A

CURRICULUM VITAE
JOYE K. LOWMAN, MD, MPH

The Southeast Permanente Medical Group
20 Glenlake Pkwy
Atlanta, GA 30328

CURRENT POSITION

THE SOUTHEAST PERMANENTE MEDICAL GROUP	Atlanta,GA
Module Lead, Urogynecology	2008 to present

MEDICAL EDUCATION

INDIANA UNIVERSITY PURDUE INSTITUTE	Indianapolis, IN
Fellowship in Female Pelvic Medicine and Reconstructive Surgery	2005-2008
ABINGTON MEMORIAL HOSPITAL	Abington, PA
Residency in Obstetrics and Gynecology	2001-2005
UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE	Philadelphia, PA
Medical Doctor	1996-2001

GRADUATE EDUCATION

INDIANA UNIVERSITY PURDUE INSTITUTE	Indianapolis, IN
Clinical Investigator, CITE program trainee	2006-2008
COLUMBIA UNIVERSITY	New York, NY
Masters of Public Health, Population and Family Health	1999-2000

UNDERGRADUATE EDUCATION

SPELMAN COLLEGE	Atlanta, GA
Bachelor of Science, Biology	1992-1996
LANCASTER UNIVERSITY	Lancaster, United Kingdom
Research Assistant	1/1995-6/1995

LICENSURE

Licensed Physician and Surgeon, Georgia

CURRENT RESEARCH ACTIVITIES

Botox in the treatment of Persistent Genital Arousal Disorder

Surgical outcomes using Type 1 polypropylene mesh

Defining the reoperation rate after total vaginectomy and colpocleisis.

Is prolonged antibiotic prophylaxis necessary when using mesh for treatment of urinary incontinence and pelvic organ prolapse?

What is the long-term success rate of the Prolift™ procedure?

Lowman, J, Latta, R. Magnesium sulfate prophylaxis in mild preeclampsia.

PRIOR RESEARCH ACTIVITIES

Retrospective cohort study evaluating the utility of magnesium sulfate prophylaxis in patients with mild pre-eclampsia.

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Effectiveness of a community education program in improving the management of Asthma in home-based childcare centers.

Defining the role of galeptin-1 in *in vitro* cord formation.

Defining the effects of keratan sulfate and chondroitin sulfate on cell migration and proliferation using wounded bovine cornea.

A new methodology for quantitating cell orientation using a grid analysis technique.

PUBLICATIONS

Katsuri S, Lowman J, Kelvin FM, Akisik F, Terry C, Hale DS. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203(5):504.e1-5

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Nosti PA, Lowman JK, Zollinger TW, Hale DS, Woodman PJ. Risk of mesh erosion after abdominal sacral colpoperineopexy with concomitant hysterectomy. Am J Obstet Gynecol.2009 Nov;201(5):541.e1-4.Epub2009 Sep20

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PRESENTATIONS

Smoking is a risk factor for mesh erosion after abdominal sacral colpoperineopexy. Presented orally at the 28th Annual American Urogynecologic Society Meeting, September 27-29, Westin Diplomat Resort, Hollywood, FL 2007. ***Won recognition/research grant for one of the top papers at the meeting**

Does the Prolift™ procedure cause dyspareunia? Presented at the 34th Annual Scientific Meeting of the Society of Gynecologic Surgeons, April 14, 2008, Savannah, GA. ***Won recognition for top research presented and $1500 travel award**

Urethrovaginal fistula repair and Martius fat pad interposition for posterior urethral disruption. Video presentation at the 34th Annual Scientific Meeting of the Society of Gynecologic Surgeons, April 14-16, Savannah, GA 2008.

Magnesium sulfate prophylaxis in mild preeclampsia. Presented orally at the Annual Resident Research Symposium, Abington, PA. 2005.

GRANT/FUNDING AWARDS

2006- Women's Health and Urology: $30,000.00
2007- Methodist Research Institute: $2,000.00
2007- AUGS Foundation Grant: $1,500.00
2008- Society of Gynecologic Surgeons Research Award: $1,500.00

EXPERTISE

- Evaluation and treatment of urinary incontinence including mid urethral slings, collagen injections and sacral neuromodulation.
- Abdominal and vaginal surgical correction of pelvic organ prolapse including vaginal reconstruction, laparoscopic reconstruction, and robotic assisted reconstruction.
- Diagnostic and operative cystoscopy.
- Rectovaginal, vesicovaginal and urethrovaginal fistula repair.
- Evaluation and management of urethral diverticulum.
- Evaluation and management of defecatory dysfunction.
- Evaluation and management of pelvic pain syndromes.

PROFESSIONAL SOCIETIES

Member, American Urogynecologic Society
Member, Society of Gynecologic Surgeons
Fellow, American College of Obstetricians and Gynecologists
Board Certified in Female Pelvic Medicine and Reconstructive Surgery
Member, National Medical Association

HONORS

Featured on V103 Radio Segment "Atlanta Up Close" November, 2014. Discussing Women's Health and Urogynecology.

Featured in Atlanta Medicine's Women's Health edition, vol. 83, No. 1, 2012. Pelvic Organ Prolapse and Urinary Incontinence.

Featured in *Best self Atlanta* magazine, Oct. 2013 pg. 51 in an article titled "Caring for Women's Total Health"

Featured in the Atlanta Tribune Oct. 2013 pg. 33 in an article titled "Dr. Joye K. Lowman Pioneers New Medical Terrain"

Featured in Ob.Gyn.News, vol. 42, No.20, October 2007 for my research on mesh erosion and smoking

Manchester Who's Who in Obstetrics and Gynecology

Franklin Fellows Scholar
NCFPR/NCSM Scholar
AUGS Foundation Research Grant Recipient
SGS Research Award Recipient

REFERENCES AVAILABLE UPON REQUEST

Appendix B

Joye Lowman

Reliance List
in Addition to Materials Referenced in Report

Patricia Hammons

Lowman Joye
Medical Literature

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Document Description [Bates Range]
[ETH.MESH.02017152 - 7158]
2005 – 2006 Gynecare Prolift Pelvic Floor Repair Systems [ETH.MESH.00484929]
2005 Prolift IFU [ETH.MESH.02341522-02341527]
2005 Prolift Patient Brochure [ETH.MESH.03905968-03905975]
2005 Prolift Profession Educational Slide Deck [ETH.MESH.09100506]
2005-06 Prof Ed Slides _ Exhibit 127
2007 Prolift Professional Education Slide Deck
2007 Prolift Surgeon's Resource Monograph
2007 Prolift Surgeons Monograph [DEFT 730.1-730.72]
2007 Prolift Surgical Technique Guide
2008 Prolift Patient Brochure
2008 Prolift Slide deck [ETH-10505 to ETH-10596]
2011 Pelvic Organ Prolapse and Stress Urinary Incontinence Patient Counseling Guide
Anatomy Videos [ETH.MESH.PM.000006]
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Anatomy Videos [ETH.MESH.PM.000057]
Anatomy Videos [ETH.MESH.PM.000068]
Anatomy Videos [ETH.MESH.PM.000088]
Anatomy Videos [ETH.MESH.PM.000089]
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Exh. 10 Gynecare Prolift IFU dated 2004 [ETH-00295 – 00300]
Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512 [ETH-01363 – 01365]

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Exh. 59 – Gynecare Prolift Pelvic Floor Repair System Physcian Learner Profile (2 pages)
FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11 [ETH.MESH.06049894-96]
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience [ETH.MESH.03736120-27]
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Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08 [ETH.MESH.02105765-02105771]
Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair [ETH.MESH.00031324 – 31325]
Lucente V. - Prospective Clinical Assessment Of The Total Vaginal Mesh (TVM) Technique For Treatment Of Pelvic Organ Prolapse - 6 And 12 Month Results [ETH-02387]
Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift [ETH.MESH.00031323]
Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS [ETH-18415]
Patient Brochure [ETH.MESH.03905968-ETH.MESH.03905975]
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